

Amendments to the Claims

The listing of claims will replace all prior versions, and listings of claims in the application.

1. (Withdrawn) A process for purifying plasmid DNA from host cell impurities to obtain a DNA product, said process comprising:

- (a) lysing host cells containing the plasmid DNA to obtain a lysate;
- (b) clarifying said lysate to obtain a clarified lysate;
- (c) ultrafiltering said clarified lysate to obtain an ultrafiltered clarified lysate;
- (d) adding a first precipitating agent in sufficient quantity to said ultrafiltered clarified lysate to obtain a precipitate of the plasmid DNA;
- (e) dissolving said precipitate to obtain a first solution;
- (f) adding a second precipitation agent in sufficient quantity to said solution to precipitate the host cell impurities and to obtain a solute containing the plasmid DNA;
- (g) transferring said solute into another buffer to obtain a second solution;
- (h) applying said second solution to an anion exchange chromatography (AEX) material to obtain an eluate containing the plasmid DNA; and
- (i) applying said eluate to a hydrophobic interaction chromatography (HIC) material to obtain the DNA product.

2. (Withdrawn) The process of claim 1, wherein said AEX material comprises a ceramic matrix.

3. (Withdrawn) The process of claim 2, wherein an average particle diameter of said ceramic matrix is about 10 μm to about 200 μm .

4. (Withdrawn) The process of claim 2, wherein an average pore size of said ceramic matrix is about 750 Å to about 3000 Å.

5. (Withdrawn) The process of claim 2, wherein an average pore size of said AEX material is about 10 Å to about 100 Å.

6. (Withdrawn) The process in claim 1, wherein an average particle diameter of resin for said HIC material is about 50 µm to about 150 µm.

7. (Withdrawn) The process in claim 1, wherein an average pore size of resin for said HIC material is about 25 nm to about 100 nm.

8. (Withdrawn) The process claim of 1, wherein said lysing in (a) is by alkaline lysis.

9. (Withdrawn) The process of claim 1, wherein said clarifying in (b) is by diatomite aided depth filtration.

10. (Withdrawn) The process of claim 1, wherein said ultrafiltering in (c) is by hollow fiber ultrafiltration.

11. (Withdrawn) The process of claim 1, wherein said first precipitating agent in (d) is polyethylene glycol (PEG).

12. (Withdrawn) The process of claim 1, wherein said second precipitating agent in (f) is ammonium acetate.

13. (Withdrawn) The process of claim 1, wherein said eluate in (h) is adjusted to a concentration of about 1 M to about 2 M ammonium sulfate.

14. (Withdrawn) The process of claim 1, wherein said HIC material in (i) contains cross-linked agarose resin.

15. (Withdrawn) The process of claim 1, further comprising concentrating said DNA product in (i) by ultrafiltration.

16. (Withdrawn) The process of claim 1, further comprising diafiltering said DNA product in (i) to remove ammonium sulfate.

17. (Withdrawn) The process of claim 1, wherein said DNA product is precipitated with ethanol.

18. (Withdrawn) The process of claim 1, which is conducted in the absence of any added enzymes, organic extractants, or mutagenic reagents.

19. (Withdrawn) The process of claim 1, further comprising sterilizing, formulating, and filling in a sterile container said DNA product.

20. (Withdrawn) The process of claim 1, wherein said host cells are bacteria.

21. (Currently Amended) A DNA product comprising from about 95% to about 100% circular plasmid DNA, wherein said DNA product contains from about 0.00001% to about [[5%]] 0.0001% RNA; from about [[0.00004 µg]] 0.00002 µg to about 0.002 µg host DNA per µg of DNA product; from about 0.00000001 µg to about 0.001 µg protein per µg DNA product; and wherein said DNA product contains ~~from about 0.00001 to about less than~~ 0.01 Endotoxin Units (EU) per µg DNA product.

22. (Currently Amended) The DNA product of claim 21, wherein said DNA product contains from about 0.00001% to about 0.0001% RNA; from about [[0.00002 µg]] 0.00004 µg to about 0.0004 µg host DNA per µg DNA product; and wherein said DNA product contains from about 0.00001 EU to about 0.0001 EU per µg DNA product.

23. (Previously Presented) The DNA product of claim 21, wherein said DNA product contains about 0.0001% RNA.

24. (Previously Presented) The DNA product of claim 21, wherein said DNA product contains about 0.00004 µg host DNA per µg of DNA product.

25. (Previously Presented) The DNA product of claim 21, wherein said DNA product contains about 0.0002 EU per µg DNA product.

26. (Previously Presented) The DNA product of claim 21, wherein said DNA product contains a mean residual endotoxin level of about 0.0001 EU per µg DNA product.

27. (Previously Presented) The DNA product of claim 21, wherein said DNA product contains an average host DNA level of about 0.0005 µg per µg DNA product.

28. (Previously Presented) A sterile container containing the DNA product of claim 21.

29. (Previously Presented) A kit comprising the DNA product of claim 21.

30. (Previously Presented) A DNA product comprising from about 95% to about 100% by weight of circular plasmid DNA, wherein said DNA product contains an amount of host cell derived impurities that is undetectable by any one of a group consisting of: LAL assay, Southern blot assay, chromatography, Northern blot assay, and ethidium bromide agarose analysis.

31. (Previously Presented) The DNA product of claim 30, wherein said DNA product is suitable for pharmaceutical use.

32. (Original) A medicament comprising the DNA product of claim 30.

33. (Original) A sterile container containing the DNA product of claim 30.

34. (Original) A kit comprising the DNA product of claim 30.

35. (Previously Presented) The DNA product of claim 30, wherein said DNA product contains an amount of host cell derived RNA undetectable by Northern blot assay, ethidium bromide agarose analysis or chromatography.

36. (Previously Presented) The DNA product of claim 30, wherein said DNA product contains an amount of host cell derived protein that is undetectable by BCA analysis.

37. (Previously Presented) The DNA product of claim 30, wherein said DNA product contains an amount of host cell derived endotoxins that is undetectable by LAL analysis.

38. (Previously Presented) The DNA product of claim 30, wherein said DNA product is essentially free of host cell derived pyrogens.

39. (Previously Presented) The DNA product of claim 30, wherein said DNA product is essentially free of host chromosomal DNA.

40. (Previously Presented) A DNA product comprising from about 95% to about 100% circular plasmid DNA, wherein said DNA product contains from about 0.00001% to about 0.0001% RNA; from about 0.00002 µg to about 0.002 µg host DNA per µg of DNA product; from about 0.00000001 µg to about 0.001 µg protein per µg DNA product; and wherein said DNA product contains from about 0.0001 to about 0.0002 Endotoxin Units (EU) per µg DNA product.